



Docket No.: 4943-103 US

The undersigned certifies that this communication is being deposited with the United States Postal Service as prepaid first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 4, 2004.

  
Diane Dunn McKay

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Application of:**

BOURASSA et al.

Serial No.: 10/796,936

Group Art Unit: TBD

Filed: March 10, 2004

Examiner: TBD

Title: METHOD AND COMPOUND TO REDUCE THE INCIDENCE OF DIABETES IN A SUBJECT WITH CHRONIC HEART FAILURE

**X**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, Applicant hereby brings to the attention of the United States Patent and Trademark Office the following documents of which Applicant has been made aware. The documents are listed on the attached PTO Form 1449. Copies of the documents are enclosed.

Applicant submits that this Information Disclosure Statement is submitted prior to a first action on the merits.

It is requested that the references be considered by the Examiner and be made of record as part of the available prior art under 37 C.F.R. § 1.104.

Respectfully submitted,


A handwritten signature in black ink, appearing to read "Diane Dunn McKay", is written over a horizontal line.

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<b>INFORMATION DISCLOSURE CITATION</b> <i>(Use several sheets if necessary)</i>		Docket Number (Optional) <b>4943-103 US</b>	Application Number <b>10/796,936</b>
*EXAMINER INITIAL		Applicant(s) <b>BOURASSA et al.</b>	
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		Filing Date <b>March 10, 2004</b>	Group Art Unit <b>TBD</b>



		The Consensus TrialStudyGroup. "Effects of Enalapril on Mortality in Severe Congestive Heart Failure." N Engl J. Med. 1987; 316: 1429-1435.
		The SOLVD Investigators. "Effect of Enalapril on Mortality and the Development of Heart Failure in Asymptomatic Patients With Reduced Left Ventricular Ejection Fractions" N Engl J. Med. 1992: 327: 685-691.
		Packer M, Poole-Wilson PA, Armstrong PW, et al. "Comparative Effects of Low Doses and High Doses of the Angiotensin Converting Enzyme Inhibitor Lisinopril on Morbidity and Mortality in Chronic Heart Failure." ATLAS study group. Circulation. 1999; 23: 2312-2318.
		Shindler DM, Kostis JB, Yusuf S, et al., "Diabetes Mellitus, A Predictor of Morbidity and Mortality in the Studies of Left Ventricular Dysfunction (SOLVD) Trials and Registry." Am J Cardiol. 1996; 77: 1017-1020.
		Bourassa MG, Gurne O, Bangdiwala SI, et al. "Natural History and Patterns of Current Practice in Heart Failure." J Am Coll Cardiol. 1993; 22(suppl A): 14A-19A.
		The SOLVD Investigators. "Effect of Enalapril on Survival in Patients With Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure." N Engl J Med. 1991; 325: 293-302.
		Lewis EJ, Hunsicker LG, Bain RP, et al. "The Effect of Angiotensin Converting-enzyme Inhibition on Diabetic Nephropathy." N Engl J Med. 1993; 329: 1456-1462.
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		The Heart Outcomes Prevention Evaluation Study Investigators. "Effects of an Angiotensin-Converting-Enzyme-Inhibitor, Ramipril, on Cardiovascular Events in High Risk Patients." N Engl J Med. 2000; 342: 145-153.
		Yusuf S, Gerstein H, Hoogwerf B, et al., "Ramipril and the Development of Diabetes." JAMA. 2001; 286: 1882-1485.
		The SOLVD Investigators. "Studies of Left Ventricular Dysfunction (SOLVD): Rationale, Design and Methods: Two Trials That Evaluate the Effect of Enalapril in Patients with Reduced Ejection Fraction." Am J Cardiol. 1990;66:315-322.

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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*EXAMINER INITIAL		American Diabetes Association. "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus." Diabetes Care. 1997; 20:1183-201.
		Gross TW, Nieto FJ, Shahar E, et al., "Hypertension and Antihypertensive Therapy as Risk Factors for Type 2 Diabetes Mellitus." N Engl J Med. 2000; 342:905-912.
		Jacob S, Rett K, Wicklmayr M, et al. "Differential Effect of Chronic Treatment With Two Beta-Blocking Agents on Insulin Sensitivity: The Carvedilol-Metoprolol Study." J Hypertens. 1996; 14:489-494.
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		Paolisso G, DeRiu S, Marrazzo G, et al., "Insulin Resistance in Hyperinsulinemia in Patients With Chronic Congestive Heart Failure." Metabolism. 1991;40:972-977.
		Sacks DB, McDonald JM. "The Pathogenesis of Type II Diabetes Mellitus: A Polygenic Disease." Am J Clin Pathol. 1996;105:149-156.
		Uehara M, Kishikawa H, Isami S, et al. "Effect on Insulin Sensitivity of Angiotensin Converting Enzyme Inhibitors with or Without a Sulphydryl Group: Bradykinin May Improve Insulin Resistance in Dogs and Humans." Diabetologia. 1994;37:300-307.
		Yang HY, Erdos EG, Levin Y. "A Dipeptidyl Carboxypeptidase That Converts Angiotensin I and Inactivates Bradykinin." Biochim Biophys Acta. 1970; 214:374-376.
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		Fryer LGD, Hajdich E, Rencurel F, et al., "Activation of Glucose Transport by AMP-Activated Protein Kinase via Stimulation of Nitric Oxide Synthase." Diabetes. 2000;49:1978-1985.

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BOURASSA et al.

**March 10, 2004**

**TBD**

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

Carlsson PO, Berne C, Jansson L. "Angiotensin II and the Endocrine Pancreas: Effects on Islet Blood Flow and Insulin Secretion in Rats." *Diabetologia*. 1998;41:127-133.

**DATE CONSIDERED**

**OF**